K070401

Exhibit #2

JUL 11 2007

ESSENTIAL DENTAL SYSTEMS

CE APPROVED PRODUCTS

89 Leuning Street
S. Hackensack
New Jersey 07606

1(800) 22-FLEXI
Tel.: (201) 487-9090
Fax: (201) 487-5120

**510(k) Summary**

| | |
|---|---|
| Name and address of sponsor of the 510(k) submission: | Essential Dental Systems, Inc.<br>89 Leuning Street<br>South Hackensack, NJ 07606 |
| Official contact person for all correspondence: | Brian Rasimick<br>Phone: 201-487- 9090<br>Fax: 201-487- 5120<br>E-mail: brasimick@edsdental.com |
| Date Prepared: | June 26, 2007 |
| Device Name: | Endo-CHX™ |
| Generic name of the device: | Root Canal Cleanser |
| Classification, Product Code and CFR Regulation Number: | Unclassified, Product Code KJJ |
| Classification Panel: | Dental |
| Predicate Device Names and 510(k) numbers: | K061689, Aquatine™ EC Endodontic Cleanser, PuriCore, Inc.<br><br>K053167, BioPure™ MTAD™ Root Canal Cleanser, Dentsply International |

**Device Description:**

Endo-CHX™ is a root canal cleanser for use in endodontic procedures. After endodontic instrumentation, the product should be used to cleanse the canal space before placement of the endodontic filling. The material should be delivered into the canal using an irrigating needle. A side-vented, closed tip irrigation needle is most preferred.

**Comparison with Predicate Device:**

Both Endo-CHX™ and Aquatine™ EC irrigate and cleanse via the mechanical action of the solution moving through the root canal system.

Both Endo-CHX™ and BioPure™ MTAD™ are combination products containing a drug component.

Endo-CHX™ is an aqueous solution of 2% chlorhexidine digluconate with surfactant and coloring. Aquatine™ EC is an aqueous hypochlorite solution (hypochlorous acid). BioPure™ MTAD™ is an aqueous doxycycline solution with citric acid and surfactant.

**Intended Use:**

Endo-CHX™ is intended to irrigate and cleanse root canal systems.

**Non-Clinical Testing:**

The performance and biocompatibility documentation provided the submission support the safety and effectiveness of the Endo-CHX root canal cleanser for the indicated uses.

**Clinical Testing:**

Not applicable

**Conclusion:**

In our opinion, Endo-CHX™ is substantially equivalent to the predicates and raises no issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2007

Essential Dental Systems, Incorporated
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K070401
Trade/Device Name: ENDO-CHX ™
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: KJJ
Dated: June 27, 2007
Received: July 3, 2007

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

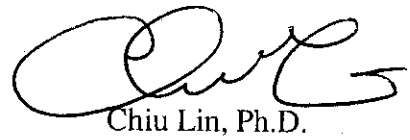
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070401

Exhibit #1

# INDICATIONS FOR USE



**510(k) Number (if known):**

**Device Name:** ENDO-CHX™

**Indications for Use:**

ENDO-CHX™ is intended to irrigate and cleanse root canal systems.

**Prescription Use __X___** **OR** **Over-The Counter Use__ _**
**(Per 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070401